UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/622,646	08/21/2000	Yasuko Ozaki	053466/0286	8792

22428 7590 12/30/2003

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER	
DAVIS, DEBORAH A	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/30/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/622,646	OZAKI ET AL.	
	Examiner	Art Unit	
	Deborah A Davis	1641	

-- The MAILING DATE of this communicati n appears n the cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 13* is/are pending in the application.

4a) Of the above claim(s) *10-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's response to the Office Action mailed March 27, 2003 (Paper #10) is acknowledged. Currently claims 1-9 and 13 pending and under consideration. Claim 13 has been added as a new claim. Claim 9 is currently amended.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 7, 8, 9 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Goto et al (Blood, Vol. 84, No 6 (September 15), 1994))

Goto et al teaches an immunoprecipitation assay that uses an anti-HM1.24 MoAb reacted with the soluble HM1.24 antigen in a sample and determining the said antigen with a molecular weight of 29 to 33 kD (p. 1922, cols. 1 and 2, 1st para). Goto et al further teaches in his assay washing and solubilizing the cells by sonication in a lysis buffer and after centrifugation, the use of normal mouse IgG and anti-mouse secondary antibody which served as a substrate for the HM1.24 MoAb (pg. 1924, col 2, 3rd para). In a flow cytometry assay the anti-HM1.24 antibody was labeled with fluorescent staining for detection purposes (p. 1923, col. 1, 2nd para).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 2, 4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Goto et al in view of Kang et al (USP# 5,656,448).

The teachings of Goto et al is set forth above and differ from the instant invention by failing to teach the soluble HM1.24 antigen protein or the anti-HM1.24 antibody bound to a support.

Kang et al teaches immunoassay methods where the antibody or antigen is bound to a solid support, wherein said supports could be plates or beads (col. 1, paras. 1-3), and solid supports are considered well known and conventional in the immunoassay art.

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to have employed a solid support (beads or plates) as taught by Kang et al in the assay methods taught by Goto et al for the convenience of contacting antigen-antibody reactions in a sample, since such solid supports are considered well known and conventional in the immunoassay art.

7. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Goto et al and Young et al (USP#6,335,183).

The teachings of Goto et al are set forth as above and differ in the instant invention in that it fails to teach the soluble HM1.24 antigen protein fused to another peptide or polypeptide.

Young et al teaches stress protein joined to fusion proteins to enhance the immune response (see abstract).

It would have been obvious to one of ordinary skill in the art at the time the instant invention was made to fuse a protein to the HM1.24 antigen for use in the assay of Goto et al to enhance an immune response for better detection and sensitivity.

Response to Arguments

2. Applicant's arguments filed September 29, 2003 have been fully considered but they are not persuasive.

Applicant's argument that the reference of Goto et al does not described the use of a "soluble" HM1.24 antigen protein is not found persuasive because the instant specification gives several examples of what can be considered a soluble HM1.24 antigen. One definition of a soluble HM1.24 antigen protein may be a protein produced by cells that inherently express them (see specification, page 19, lines 17-22). The instant reference of Goto et al teaches the HM1.24 antigen is expressed by mature B cells (see page 1929, column 1, paragraph 1). Further, the ability of a protein to become solubilized is an inherent feature of the HM1.24 antigen.

Applicant's argument that Examiner has failed to establish a prima facie case of obviousness concerning the 103 rejection of Goto in view of Kang and Goto in view of Young, asserting that the reference of Goto has not taught a "soluble" HM1.24 antigen is not found persuasive for the same reasons aforementioned above. Therefore, it is the Examiner's position that the references meet the claimed limitations of the instant invention and rejections are hereby maintained.

Conclusion

No claims are allowed.

3. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is (703) 308-4427. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

Deborah A. Davis
CM1, 7D16
December 18, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

12/24/03